



EC DECLARATION OF CONFORMITY

Product: GD19 POWDER FREE EXAMINATION NITRILE GLOVES

SANTEX 2000 INTERNACIONAL SL in Paseo de la Castellana, 141 plantas 8 y 9, Cuzco IV 28046 Madrid, with SRN: ES-MF-000026359 declares that:

This declaration of conformity is issued under the sole responsibility of the manufacturer.

The afore mentioned materials and products have been revised in accordance with the self-declaration of conformity requirements for EC marking according to the Medical Devices Regulation (EU) 2017/745, and standards EN 455-1, EN 455-2, EN 455-3, EN 455-4.

In the transformation and production of the film, all current health standards are followed, being the facilities where it has been manufactured certified with the international harmonized standard ISO 13485.

According annex VIII Regulation (EU) 2017/745, It is a class I medical device and Basic UDI-DI: 84370NITRILOTV.

SIGNATURE:

A handwritten signature in blue ink, consisting of several vertical strokes followed by a diagonal line crossing them.